



August 5, 2003

United States  
Department of  
Agriculture

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 03-11**

Marketing and  
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Animal and Plant  
Health Inspection  
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Veterinary Services

Center for Veterinary  
Biologics  
Suite 104  
510 South 17<sup>th</sup> Street  
Ames, IA 50010  
(515) 232-5785  
FAX (515) 232-7120

Subject: Issuance of a Conditional License for Mycobacterium Bovis Gamma Interferon Test Kit for Cervids

To: Biologics Licensee, Permittees, and Applicants  
Veterinary Services Management Team  
Directors, Center for Veterinary Biologics  
Area Veterinarians in Charge, VS  
State Veterinarians

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Biocor Animal Health, Inc., Establishment No. 462, Omaha, Nebraska, for the manufacture and distribution of Mycobacterium Bovis Gamma Interferon Test Kit for Cervids.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product may be issued. The regulations in 9 CFR Part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstances. There is no licensed diagnostic test kit currently available that provides a rapid *in vitro* assay for the detection and diagnosis of bovine tuberculosis in cervids.

This conditional license was issued following the acceptance of data demonstrating adequate kit performance for the detection of *M. bovis* infection in cervids. The firm is required to collect additional field data and further validate the potency test before APHIS will issue a regular product license. The conditional license will expire in one year.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics



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